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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/015,399	01/29/1998	ARI HINKKANEN	2328-111	5673

6449 7590 05/05/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/05/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/015,399

Applicant(s)
Hinkkanen

Examiner
G.R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, 17-20, 23, 24, 27, and 28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 7-10, 17, 18, and 20 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 19, 23, 24, 27, and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: Paper No. 3

DETAILED ACTION

1. Applicant's amendment and remarks, filed 3/03/03, are acknowledged.
2. Claims 1-3, 5-10, 17-20, 23-24, and 27-28 are under examination.
3. In view of Applicant's amendment, filed 3/03/03, the previous rejection under the second paragraph of 35 U.S.C. 112 has been withdrawn. The rejection under the first paragraph of 35 U.S.C. 112 for the recitation of glutamic acid decarboxylase and islet cell antigen has also been withdrawn.
4. Regarding the drawings, Applicant is advised that the Form PTO-948, dated 4/30/98 did indeed indicate that the original drawings were found acceptable by the draftsman. However, in Paper No. 3, filed 05/22/98, Applicant submitted amended drawings for consideration comprising corrections hand-written in red ink. As set forth previously, the amending of "Sfg I" to Sgf I" in the corrections of Figure 1 is objected to and will not be allowed.

Applicant asserts that no corrections have been proposed by Applicant, however, Paper No. 3, filed 05/22/98, would seem to indicate otherwise. A copy of Applicant's submission is enclosed.
5. Note that while it should have been clear in the previous Office action that all claims reciting the term "affinity binding pair" were rejected under the first paragraph of 35 U.S.C. 112, not all of the rejected claims were listed in the rejection. Accordingly, the correction is made here and the Office action has not been made final.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 5, 6, 23, 24, 27, and 28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper No. 32, mailed 12/02/02.

Applicant arguments, filed 3/03/03, have been fully considered but are not found persuasive. Applicant argues that the term "affinity binding pair" is disclosed at page 6 of the specification and that the specification discloses how such a pair would operate to enable the binding of a fusion protein to a solid phase.

Applicant is advised that the rejection was not made for a lack of enablement, but rather for a lack of adequate written description. While the term is disclosed in this instance, it remains undefined.

Applicant argues that additional affinity binding pairs would be known to one of ordinary skill in the art. Such pairs include, for example, glutathione S-transferase-glutathione and maltose binding protein-amylase.

Applicant is advised that post-filing examples cannot serve as an adequate definition for an undefined term found in the specification. Absent any sort of definition, the "affinity binding pair" genus would encompass any compounds or compositions that bind each other, conceivably ranging from antibodies and their ligands to ionic salts, none of which are disclosed in the specification.

8. Claims 19 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed (new matter), for the reasons of record as set forth in Paper No. 32, mailed 12/02/02.

Applicant arguments, filed 3/03/03, have been fully considered but are not found persuasive. Applicant argues that "although lanthanide labels are indicated to be preferable, the specification does in fact recite that any suitable label can be used. In that regard, Applicant asserts that one ordinary skill in the art would recognize that the recited lanthanide labels are merely exemplary of the various types of suitable labels that could be employed in accordance with the invention. For example, page 12, lines 5-8 of the specification indicate that a

radiolabel, while less preferable than a lanthanide label, is in fact suitable for use in the claimed invention."

It is the Examiner's position that even though the specification may recite that any suitable label can be used, claims drawn to specific types of labels are not supported. Regarding the assertion that radiolabels are disclosed, at page 12, lines 5-8, it is disclosed that lanthanide labels are generally advantageous compared to radiolabels. There is no disclosure that radiolabels are specifically encompassed by the claimed invention. Regarding fluorescent labels, they are in no way disclosed. Accordingly, the rejection is maintained.

9. Claims 1-3, 7-10, 17, 18, and 20 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
April 30, 2003